Amendments to the Drawings:

The attached drawing sheet (Appendix A) includes changes to the Figure. This sheet,

which includes the Figure, replaces the original sheet including FIG. 1. In the Figure, reference

to "FIG. 1" has been deleted.

Attachment/Appendix A:

Replacement Sheet

Annotated Sheet Showing Changes

25530241.1

- 7 -

#### II. A Response to the Office Action:

#### A. Status of the Specification

The specification has been amended as suggested by the Action. For example, the specification now refers to "the Figure" instead of "Fig. 1." Applicants also submit corrected drawing sheets (See Appendix A) in compliance with 37 CFR 1.121(d) along with this response. The Abstract has been amended at the suggestion of the Action. The trademark name "ORMA" has been capitalized in the specification.

Applicants request that the objections to the specification be withdrawn.

#### B. Status of the Claims

Claims 20-26 were pending when the Office Action dated November 4, 2004, issued from the U.S. Patent Office. Claims 20, 21, and 23-26 have been amended, claim 22 has been canceled, and claims 27-28 have been added. Support for these claims can be found throughout the specification and claims as originally filed. No new matter has been added. Claims 20-21 and 23-28 are currently pending.

#### C. Status of the Drawings

The Action objected to the drawings "because only a single view (i.e., the drawing labeled as FIGURE 1) is used to illustrate the claimed invention..." The Action, page 2. The drawings have been amended at the request of the Action. Attached as Appendix A is a Replacement Sheet and an Annotated Sheet showing the changes.

Applicants request that the objections to the drawings be withdrawn.

#### D. Objection to Claims 21-26 Is Overcome

The Action objects to claims 21-26 because the word "ophthalmic" is misspelled, "opthalmic." Correction of this misspelling is addressed in the amendments to the claims. Applicants request that this objection be withdrawn.

## E. The Indefiniteness Rejections Are Overcome

The Action rejects claims 23-25 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Action contends that the phrase "the additive" in claim 20 lacks antecedent basis.

Applicants disagree. Claim 20 satisfies all of the requirements under 35 U.S.C. § 112, second paragraph.

In an effort to further the prosecution in this case, however, Applicants have revised the claims to address the Action's concerns. Applicants request that this indefiniteness rejection be withdrawn.

#### F. The Anticipation Rejections Are Overcome

The Action presents five separate anticipation rejections based on: (1) U.S. Patent No. 6,551,710 to Chen *et al.*; (2) U.S. Patent Application No. 2002/0009599 to Welch *et al.*; (3) U.S. Patent No. 4,454,170 to Goepfert *et al.*; (4) U.S. Patent No. 5,770,259 to Parker *et al.*; and (5) U.S. Patent No. 5,013,608 to Guest *et al.* Each of these rejections are addressed in the following five subsections.

Applicants note that in order to establish anticipation, the Action must show that a single reference discloses every element of Applicants' claimed invention, either expressly or inherently. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir.

25530241.1 - 9 -

2001); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987). The Examiner carries this burden. See In re Sun, 31 U.S.P.Q.2d 1451,1453 (Fed. Cir. 1993).

## 1. Claims 20, 21, and 23-26 Are Not Anticipated By Chen et al.

The Action rejects claims 20, 21, and 23-26 as being anticipated by Chen *et al*. The Action contends that this reference discloses "an ophthalmic lens comprising an optically transparent substrate, wherein the substrate is coated, on at least one face, with an optically transparent impregnatable thin film adhering to the substrate." The Action page 6.

Applicants disagree. Claims 20, 21 and 23-26 are not anticipated by the Chen et al. reference.

Applicants presently claim "[a]n ophthalmic lens comprising an optically transparent substrate, wherein the substrate is coated, on at least one face, with an optically transparent impregnatable thin film, adhering to the substrate and comprising an impregnation composition, said thin film being produced from a polymer material obtained from a latex, wherein said thin film comprises a thickness of less than  $5\mu$ m." Claim 20 (emphasis added). Dependent claim 21 notes that the latex can be a polyurethane latex.

Chen et al., by contrast, appears to disclose a transparent substrate coated with a primer layer, which can be imbibed with a dye. See Chen et al., col. 2, lines 15-18 and col. 3, lines 28-29. The primer layer is produced from a polymer material:

An ultraviolet irradiation curable primer composition for coating optical articles, in which the primer composition comprises: a dithiol or polythiol compound, and an allyl or vinyl monomer. The coating composition can further comprise photochromic dyes and additional polymerizable monomers.

*Id.* at Abstract. There does not appear to be any disclosure in this reference that the primer layer is produced from a latex, much less a polyurethane latex.

25530241.1 - 10 -

Chen et al. also does not appear to disclose Applicants' "impregnation composition," much less an "impregnation composition" that "contains an agent for retaining the additive, preferably a crossliking agent." See Claims 20 and 24, respectively. Rather, the polymerizable comonomers in Chen et al. (which the Action apparently contends are retaining agents), are initially present in the primer coating composition (and not in the impregnation composition), i.e., in the composition prior to polymerization. Because of this, these polymerizable comonomers will copolymerize with the other monomers during polymerization and curing of the primer coating composition. See Chen et al., col. 11, lines 49-60. Consequently, when the polymerized and cured primer coating is impregnated, the composition will not contain any retaining agent. Additionally, there will be no polymerizable comonomers present in the cured primer coating because they will have been already engaged in the polymerization and curing process of the primer coating.

Finally, when a dye is incorporated into the primer coating of Chen *et al.*, the primer coating has preferably a thickness of about 10 to 75 $\mu$ m. See id. at col. 3, lines 5-7. This is far higher than the upper limit of Applicants' claimed "less than  $5\mu$ m."

For at least the above reasons, Chen *et al.* fails to disclose every element of Applicants' claimed invention. Applicants request that the rejection of claims 20-21 and 23-26 under 35 U.S.C. § 102(e) as being anticipated by Chen *et al.* be withdrawn.

## 2. Claims 20-26 Are Not Anticipated By Welch et al.

The Action rejects claims 20-26 as being anticipated by Welch *et al*. The Action contends that this reference discloses "an ophthalmic lens comprising an optically transparent substrate, wherein the substrate is coated, on at least one face, with an optically transparent impregnatable thin film adhering to the substrate." The Action page 7.

25530241.1 - 11 -

Applicants disagree. Claims 20-26 are not anticipated by the Welch et al. reference.

This reference appears to disclose preparing a photochromic polyurethane coating having an acceptable microhardness Fischer. This apparently occurs by combining a polycarbonate polyol of a molecular weight of 500 to 5000 g/mole, optionally, a different polyol having a molecular weight of at least 500g/mole, an isocyanate, a photochromic compound and optionally a catalyst for producing a photochromic polyurethane coating. *See* Welch *et al.*, ¶ [0007]. The photochromic compounds can be incorporated in the cured coating by imbibation, permeation, or any other transfer process known from the skilled person.

Welch et al. fails to disclose "said thin film being produced from a polymer material obtained from a latex, wherein said thin film comprises a thickness of less than  $5\mu$ m." Claim 20. For instance, Welch et al. discloses the direct production for forming a polyurethane coating by reacting specific polyols with an isocyanate, and optionally a catalyst. There does not appear to be any disclosure in this reference to form a polyurethane coating from a polyurethane latex, i.e. an aqueous dispersion of already formed polyurethane polymer particles.

Additionally, the cured coating of Welch *et al.* appears to have a thickness ranging from 5 to 200  $\mu$ m, preferably 5 to 100 $\mu$ m, better 10 to 40  $\mu$ m, for example 30 $\mu$ m and even better 10 to 25  $\mu$ m, for example 20  $\mu$ m (see paragraph (0067]). There is no apparent disclosure of Applicants claimed "less than 5 $\mu$ m."

Finally, Welch *et al.* only incidentally mentions the possibility of impregnating the cured coating with a photochromic impregnation composition (paragraph [0062]). Contrary to the Examiners statement, paragraphs [0058] [0064] of Welch et al. do not disclose an impregnation composition comprising a dispersion of a dying additive in a diluting medium; rather it concerns a polymerizable composition containing a dye designed to (after polymerization) form the

25530241.1 - 12 -

polyurethane coating itself. The same is true regarding paragraph [0065] of Welch et al., which merely mentions that additional classical additives can be incorporated in the composition for forming the photochromic polyurethane coating, but does not disclose at all an impregnation composition for an already formed coating and which would contain a retaining agent.

For at least the above reasons, Welch *et al.* fails to disclose every element of Applicants' claimed invention. Applicants request that the rejection of claims 20-26 under 35 U.S.C. § 102(e) as being anticipated by Welch *et al.* be withdrawn.

## 3. Claims 20-23 and 25 Are Not Anticipated By Goepfert et al.

The Action rejects claims 20-23 and 25 as being anticipated by Goepfert *et al*. The Action contends that this reference discloses "an ophthalmic lens comprising an optically transparent substrate, wherein the substrate is coated, on at least one face, with an optically transparent impregnatable thin film produced from a polymer material." The Action page 8.

Applicants disagree. Claims 20-23 and 25 are not anticipated by the Goepfert *et al.* reference.

Goepfert appears to disclose a process for coloring a polyurethane sheet. The sheet is optionally laminated on a transparent substrate. The process includes dipping the sheet in a coloration bath and then fixing the colorant. The coloration composition appears to be simply deposited on the polyurethane sheet surface and then the colorant is fixed on the surface. Stated another way, the reference does not appear to disclose Applicants' claimed "impregnatable thin film."

This reference also does not appear to disclose Applicants' claimed "thin film being produced from a polymer material obtained from a latex" or a "polyurethane latex." Additionally, the polyurethane sheet in Goeppert *et al.* appears to have a thickness of 450µm

25530241.1 - 13 -

(column 7, lines 44-45). There is no disclosure of Applicants' claimed "less than  $5\mu m$ " thickness.

For at least the above reasons, Goeppert *et al.* fails to disclose every element of Applicants' claimed invention. Applicants request that the rejection of claims 20-23 and 25 under 35 U.S.C. § 102(b) as being anticipated by Goeppert *et al.* be withdrawn.

## 4. Claims 20-26 Are Not Anticipated By Parker et al.

The Action rejects claims 20-26 as being anticipated by Parker *et al*. The Action contends that this reference discloses "an ophthalmic lens comprising an optically transparent substrate, wherein the substrate is coated, on at least one face, with an optically transparent impregnatable thin film adhering to the substrate." The Action page 8.

Applicants disagree. Claims 20-26 are not anticipated by the Parker et al. reference.

Contrary to the Action's contentions, Parker et al. merely discloses a coloring process of an ophthalmic lens which includes coating a transparent substrate with a resin based colored coating. See, e.g., Parker et al., Abstract. There does not appear to be any disclosure of Applicants' claimed invention such as "an optically transparent substrate,...coated on at least one face, with an optically transparent impregnatable thin film."

For at least the above reasons, Parker *et al.* fails to disclose every element of Applicants' claimed invention. Applicants request that the rejection of claims 20-26 under 35 U.S.C. § 102(b) as being anticipated by Parker *et al.* be withdrawn.

## 5. Claims 20, 21, and 23-25 Are Not Anticipated By Guest et al.

The Action rejects claims 20, 21, and 23-25 as being anticipated by Guest et al. The Action contends that this reference discloses "an ophthalmic lens comprising an optically

25530241.1

transparent substrate, wherein the substrate is coated, on at least one face, with an optically transparent impregnatable thin film produced from a polymer." The Action page 9.

Applicants disagree. Claims 20, 21, and 23-25 are not anticipated by the Guest *et al.* reference.

Guest et al. appears to disclose a substrate comprising a tintable abrasion resistant coating. Guest et al., Abstract. The tintable abrasion resistant coating is a silicon coating containing colloidal silica which includes compounds improving tintability. See id. at col. 4, lines 1-50. Tinting is effected by immersion of the coated substrate in a hot coloring bath.

There does not appear to be any disclosure in this reference of Applicants' claimed "thin film being produced from a polymer material obtained from a latex and having a thickness of less than  $5\mu$ m"—much less a "polyurethane latex." See Claims 20 and 21, respectively.

Additionally, the coloring bath in Guest *et al.* does not appear to contain any retaining agent (see Applicants' dependent claim 23). In fact, the cross-linking agent in this reference appears to be contained within the initial coating composition and is consumed once the coating has been formed.

For at least the above reasons, Guest *et al.* fails to disclose every element of Applicants' claimed invention. Applicants request that the rejection of claims 20, 21, and 23-25 under 35 U.S.C. § 102(b) as being anticipated by Guest *et al.* be withdrawn.

### G. The Obviousness Rejection is Overcome

#### 1. A Summary of the Rejection

The Action rejects claims 20-26 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,316,791 to Farber *et al.* in view of Parker *et al.* and Goepfert *et al.* The Action contends that Farber discloses "an ophthalmic lens comprising an optically transparent substrate,

25530241.1 - 15 -

wherein the substrate is coated, on at least one face, with an optically transparent impregnatable thin film produced from a polymer material, specifically a polyurethane latex primer. The Action, however, concedes that Farber et al. fails to disclose "that the polyurethane primer comprises an 'impregnation composition', specifically a solution or dispersion, in a diluent medium, of an additive (e.g. a dye) to be incorporated." The Action, page 5. In an effort to supplement the deficient teachings of this reference, the Action relies on Parker et al. and Goepfert et al. and concludes that it would have been obvious to one of ordinary skill in the art to impregnate polyurethane latex primer coating of Farber et al. with an 'impregnation composition' comprising a solution or dispersion of a dye in a diluent medium." The Action, pages 11-12.

Applicants disagree. Claims 20-26 are not obvious over the cited references.

## 2. The Action Has Not Established a Prima Facie Case of Obviousness

It is well settled that "[t]he examiner bears the initial burden of factually supporting any prima facie case of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of non-obviousness." MPEP § 2142.

To establish a *prima facie* case of obviousness, the Examiner must show: (1) the prior art reference teaches or suggests all of the claim limitations; (2) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (3) a reasonable expectation of success that such modifications would work. *Id.*; *see also In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). With respect to the motivation to combine the references, the MPEP states "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious

25530241.1 - 16 -

unless the prior art also suggests the desirability of the combination." MPEP § 2143.01. If any one of the three elements is missing, a *prima facie* case of obviousness cannot be established.

# i. The Cited References Fail to Disclose Every Element of Applicants' Claimed Invention

A necessary requirement in establishing a *prima facie* case of obviousness mandates a showing by the Action that every element is taught or suggested by the cited references. *See* MPEP § 2142. This has not been done.

The cited references fails to disclose at least Applicants' claimed "impregnatable thin film." Applicants have previously described this deficiency in the Parker and Goepfert *et al.* references. Those arguments are incorporated into this section by reference.

As for Farber et al., it appears to disclose a process for improving the impact resistance of a substrate made of a plastic material by applying on one of the substrate surfaces an aqueous polyurethane dispersion to form a primer layer and on the primer layer an abrasion-resistant layer. This reference notes that the primer layers used are particularly useful when the hard protective layer (abrasion-resistant layer) is colored using a coloring bath at elevated temperatures. See, e.g., Farber et al. at col. 4, lines 56-58.

There is simply no disclosure in this reference of an "impregnatable thin film" or such a film "being produced from a polymer material obtained from a latex" or "polyurethane latex." Again, it is the hard coating in Farber *et al.* that is tinted.

Because all three of the cited references when combined fail to disclose every element of Applicants' invention, a *prima facie* case of obviousness has not been established by the Action.

See MPEP § 2142. Therefore, the present obviousness rejection cannot be maintained.

ii. There is No Motivation to Modify or Combine the Cited References to Include Applicants' Claimed "impregnatable thin film"

25530241.1

A second element necessary to establish a *prima facie* case of obviousness requires a showing by the Action of a motivation to modify or combine the cited references to include Applicants' claimed "impregnatable thin film." This has not been done.

The Action's contentions that Parker et al. discloses that "in the art of producing coated, tinted ophthalmic lenses (i.e., a process analogous to that of Farber et al.), either (1) the primer coating on the lens can be tinted and then coated with an untinted hard coating, or (2) the primer coating on the lens can be untinted and then coated with a tinted hard coating" is difficult to understand. It appears that the Action is asserting that Parker et al. discloses the functional equivalency of: 1) coloring a primer coating, and 2) coloring a hard coat covering a primer coating.

This reasoning appear to be incorrect. The portion of the Parker *et al.* reference quoted by the Examiner states: "[a plastic material lens] having a tinted primer layer 11a or one of its surfaces and an untinted coating according to the invention which provides a hard top coat 11b." As indicated above by Applicants, the tinted coating of Parker *et al.* are not impregnable coatings as claimed by Applicants. Rather, the Parker *et al.* coatings are directly formed from a polymerizable and curable composition including a colorant. Consequently, at most Parker *et al.* would suggest to use in the Farber *et al.* process primer layer directly formed from a curable and polymerizable composition containing a colorant and not Applicants' claimed "impregnatable thin film ... being produced from a polymer material obtained from a latex and comprising a thickness of less than 5µm."

Goepfert et al. similarly fails. There is no motivation to combine the teachings of Goepfert et al. with those of Farber et al. Goepfert et al. discloses a process for coloring a polyurethane sheet, which as previously mentioned, is not Applicants' claimed "thin film." The

25530241.1 - 18 -

lack of a motivation to combine these references is evident because Farber et al. never envisages a tinted impact resistant layer (PU); rather it concerns a tinted hard coat layer. See Farber et al., Abstract.

Because there is no motivation to combine the cited references, a second element necessary in establishing a *prima facie* case of obviousness has not been established. Therefore, the present obviousness rejection cannot be maintained.

## iii. There is No Reasonable Expectation of Success that the Combinations of the Cited References Would Work

A third element necessary to establish a *prima facie* case of obviousness requires a showing by the Action of a reasonable expectation of success that the combination of the disclosure of Farbet *et al.* with those of Parker *et al.* and Goepfert *et al.* would work. This has not been done.

There is no reasonable expectation of success that the claimed combination of references would work. Again, none of the cited references used for obviousness appear to disclose Applicants' claimed "impregnatable thin film...being produced from a polymer material obtained from a latex and comprising a thickness of less than 5µm." There is simply no indication in these references that Applicants' claimed composition would work.

Because all three requirements for establishing a *prima facie* case of obviousness have not been established, the present obviousness rejection cannot be maintained. Applicants request that the rejection of claims 20-26 under 35 U.S.C. § 103(a) as being obvious over the cited references be withdrawn.

#### H. Conclusion

25530241.1 - 19 -

Applicants believe that the present document is a full and complete response to the Office Action dated November 4, 2004. The present claims are in a condition for allowance, and such favorable action is requested.

III. Petition for a Three-Month Extension of Time

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of three

months to and including May 4, 2005, in which to respond to the Office Action dated November

4, 2004. Pursuant to 37 C.F.R. § 1.17, a check in the amount of \$1020.00 is enclosed, which is

the process fee for a three-month extension of time for a large entity status. If the check is

inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required

for any reason relating to the enclosed materials, or should an overpayment be included herein,

the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski

Deposit Account No. 50-1212/ESSR:060USD1.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3035 with any

questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

Mark B. Wilson

Reg. No. 37,259 Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue, Suite 2400

Austin, Texas 78701

(512) 536-3035

(512) 536-4598 (facsimile)

Date:

May 4, 2005



Annotated Sheet Showing Changes

